K061429

510(k) Summary

JUL 25 2006

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

807.92(a)(1)

Submitter Information

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Date: May 22, 2006

807.92(a)(2)

Trade Name: Dynamic MRI Software Option for C-scan, E-scan XQ and E-scan Opera

Common Name: System, Nuclear Magnetic Resonance Imaging

Classification Name(s): Magnetic Resonance Diagnostic Device

Classification Number: 90LNH

807.92(a)(3)

Predicate Device(s)

Esaote	C-scan	K040877
Esaote	E-scan XQ	K032121
Esaote	E-scan Opera	K060956
Siemens Medical Systems	Perfusion Package for Magnetom Vision and Symphony MR Systems	K984224
GE Medical Systems	Advantage Windows with FuncTool Option	K960265

807.92(a)(4)

Device Description

The Dynamic MRI Software Option is a software package intended to be used with the Esaote C-scan, E-scan XQ and E-scan Opera MRI systems, cleared via K040877 K032121 and K060956, respectively. The software package allows the acquisition of MR dynamic image datasets and the post processing display of temporal variations in the acquired image datasets, showing changes in image contrast over time.

It provides time intensity data, calculates the interpolation curve of the data, its maximum slope and its asymptotic value. These data, when interpreted by a trained physician, yield information that may assist diagnosis.

C-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the limbs and joints. It is intended for imaging portions of the arm, including the hand, wrist, forearm and elbow, but excluding the upper arm, and imaging portions of the leg, including the foot, ankle, calf and knee, but excluding the thigh.

E-scan XQ is a magnetic resonance (MR) system that produces transversal, sagittal and coronal and oblique cross–section images of the limbs and joints. It is intended for imaging portions of the arm, including the hand, wrist, forearm, elbow, upper arm and shoulder, and imaging portions of the leg, including the foot, ankle, calf, knee, thigh and hip.

E-scan Opera is a magnetic resonance (MR) system that produces transversal, sagittal and coronal and oblique cross–section images of the limbs and joints. It is intended for imaging portions of the arm, including the hand, wrist, forearm, elbow, upper arm and shoulder, and imaging portions of the leg, including the foot, ankle, calf, knee, thigh and hip.

The C-scan, E-scan XQ and E-scan Opera MR images correspond to the spatial distribution of protons (hydrogen nuclei) that determine magnetic resonance properties and are dependent on the MR parameters, including spin–lattice relaxation time (T1), spin–spin relaxation time (T2), nuclei density, flow velocity and "chemical shift". When interpreted by a medical expert trained in the use of MR equipment, the images can provide diagnostically useful information.

807.92(a)(5)

Intended Use(s)

The Dynamic MRI Software Option for the C-scan, E-scan XQ and E-scan Opera MRI Systems allows the acquisition of MR dynamic image datasets and the post processing display of temporal variations in the acquired datasets, showing changes in contrast over time. Its purpose is to provide time intensity curves that support the diagnostic process. These images when interpreted by a trained physician, yield information that may assist in diagnosis.

807.92(a)(6)

Technological Characteristics

The addition of the Dynamic MRI Software Option, reflected in this 510(k), does not alter the fundamental scientific technology of the C-scan system, cleared via K040877, E-scan XQ system, cleared via K032121 and E-scan Opera system, cleared via K060956.

Substantial Equivalence Comparison Tables

Characteristic	Dynamic MRI Software Option for C-scan, E-scan XQ and E-scan Opera	C-scan K040877	E-scan XQ K032121	E-scan Opera K990968	Comments
Pulse sequences	Spin Echo T1 (SET1) Gradient Echo (GE)	Spin Echo T1 (SET1) Gradient Echo (GE)	Spin Echo T1 (SET1) Gradient Echo (GE)	Spin Echo T1 (SET1) Gradient Echo (GE)	Unchanged
Sequence parameters	Spin Echo 16 TR from 40 ms to 5000 ms, step 20 ms TE fixed at 16 ms minimum FOV 100 mm minimum slice thickness 2 mm Gradient Echo 6 TR from 40 ms to 5000 ms, step 20 ms TE fixed at 6 ms FA from 10° to 90°, step 5° minimum FOV 100 mm minimum slice thickness 2 mm	SET1 TR from 40 ms to 5000 ms, step 20 ms TE from 18 ms to 34 ms, step 2 ms minimum FOV 100 mm minimum slice thickness 2 mm GE TR from 40 ms to 5000 ms, step 20 ms TE from 8 ms to 24 ms, step 2 ms FA from 10° to 90°, step 5° minimum FOV 100 mm minimum slice thickness 2 mm	SET1 TR from 50 ms to 5000 ms, step 10 ms TE from 18 ms to 34 ms, step 2 ms minimum FOV 100 mm minimum slice thickness 2 mm GE 10 TR from 35 ms to 5000 ms, step 5 ms TE fixed at 10 ms FA from 10° to 90°, step 5° minimum FOV 130 mm minimum slice thickness 2 mm	SET1 TR from 50 ms to 5000 ms, step 10 ms TE from 18 ms to 34 ms, step 2 ms minimum FOV 100 mm minimum slice thickness 2 mm GE 10 TR from 35 ms to 5000 ms, step 5 ms TE fixed at 10 ms FA from 10° to 90°, step 5° minimum FOV 130 mm minimum slice thickness 2 mm	They are a particular version of the Spin Echo T1 and Gradient Echo standard sequences for obtaining high acquisition speed and contrast resolution.

Characteristic	Dynamic MRI Software Option for C-scan, E-scan XQ and E-scan Opera	Perfusion package for Magnetom Vision and Symphony MR systems - K984224
Product code	LNH	LNH
Indications for use	The Dynamic MRI Software Option for the C-scan, E-scan XQ and E-scan Opera MRI Systems allows the acquisition of MR dynamic image datasets and the post processing display of temporal variations in the acquired datasets, showing changes in contrast over time. Its purpose is to provide time intensity curves that support the diagnostic process. These images when interpreted by a trained physician, yield information that may assist in diagnosis.	The Perfusion Package for the Magnetom Vision and Symphony MR Systems is a software package which allows the display of temporal variations in dynamic MR Datasets, showing changes in contrast over time. Its purpose is to provide either time intensity curves or the creation of parametric images for parameters like time to peak that support the diagnostic process. These images when interpreted by a trained physician, yield information that may assist in diagnosis. One clinical application where this could be useful is the diagnosis of lesions by temporal analysis of tumor enhancement.
Device Description	The Dynamic MRI Software Option is intended to acquire MR dynamic image datasets and uses a post processing procedure for display of temporal variations in the acquired datasets for the C-scan, E-scan XQ and E-scan Opera MRI Systems.	The Perfusion Package is a post processing option for the Magnetom Vision and Symphony MR Systems
Technological Characteristics	The magnet, RF system and gradient system of C-scan, E-scan XQ and E-scan Opera MRI Systems configured with the Dynamic MRI Software Option is substantially equivalent to the standard C-scan, E-scan XQ and E-scan Opera Systems.	The magnet, RF system and gradient system of the Magnetom Vision and Symphony configured with the Perfusion Package is substantially equivalent to the standard Magnetom Vision and Symphony Systems.
Input data	Dynamic MR datasets Single or multi-slice datasets	Dynamic MR datasets
Features	Display of temporal variations in dynamic MR datasets, showing changes in image contrast over time	Display of temporal variations in dynamic MR datasets, showing changes in image contrast over time
Image Processing	Time intensity data and time intensity interpolation curve, its maximum slope and its asymptotic value	Time intensity curves Parametric images for parameters like time to peak

Characteristic	Dynamic MRI Software Option for C-scan, E-scan XQ and E-scan Opera	FuncTool Option K960265
Product code	LNH	LLZ
Indications for use	The Dynamic MRI Software Option for the C-scan, E-scan XQ and E-scan Opera MRI Systems allows the acquisition of MR dynamic image datasets and the post processing display of temporal variations in the acquired datasets, showing changes in contrast over time. Its purpose is to provide time intensity curves that support the diagnostic process. These images when interpreted by a trained physician, yield information that may assist in diagnosis.	The FuncTool option to the Advantages Windows workstation is a software module that provides supplemental information to those images extracted from CT and MR temporal datasets.
Device Description	The Dynamic MRI Software Option is intended to acquire MR dynamic image datasets and uses a post processing procedure for display of temporal variations in the acquired datasets for the C-scan, E-scan XQ and E-scan Opera MRI Systems.	FuncTool is a functional imaging software package, which allows to display the temporal variation in dynamic CT and MR datasets. Single or multi-slice datasets, with equally spaced time interval are used for input. The purpose is to provide Time Intensity Curves and parametric images that provide clinical information for diagnosis purposes. This software is used during post-processing of MR and CT images on GE's CT and MR Systems.
Input data	Dynamic MR datasets Single or multi-slice datasets with equally or differently spaced time interval	Dynamic CT and MR datasets Single or multi-slice datasets, with equally spaced time interval
Features	Display of temporal variations in dynamic MR datasets, showing changes in image contrast over time	Display of temporal variations in dynamic CT and MR datasets, showing changes in image contrast over time
Image Processing	Time intensity data and time intensity interpolation curve, its maximum slope and its asymptotic value	Time intensity curves and parametric images

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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JUL 25 2006

Esaote, S.p.A.
% Ms. Carri Graham
Consultant
Anson Group, LLC
11460 N Meridian St., Ste 150
CARMEL IN 46032

Re: K061429
Trade/Device Name: Dynamic MRI Software for C-scan, E-scan, XQ and E-scan Opera
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: May 22, 2006
Received: May 23, 2006

Dear Ms. Graham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061429

Device Name: Dynamic MRI Software Option for C-scan, E-scan XQ and E-scan Opera

Indications for Use:

The Dynamic MRI Software Option for C-scan, E-scan XQ and E-scan Opera MRI Systems allows the acquisition of MR dynamic image datasets and the post processing display of temporal variations in the acquired datasets, showing changes in contrast over time. Its purpose is to provide time intensity curves that support the diagnostic process. These images when interpreted by a trained physician, yield information that may assist in diagnosis.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061429